

Attorney Docket No.: DC-0251
Inventor: Wade and Demian
Serial No.: 09/720,078
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REMARKS

Claims 32-37 are pending in the instant application. Claims 32-37 have been rejected. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112

Claims 32-37 have been rejected under 35 U.S.C. 112, first paragraph. The Examiner suggests that the specification as originally filed does not provide support for the invention as now claimed: "an adjuvant which induces a cytotoxic T lymphocyte response to the selected antigen of (i)" as recited in claim 32. The Examiner suggests that Applicants' amendment filed 7/6/06 simply states that no new matter has been added, but does not provide sufficient direction to the written support in the specification as filed for this newly added limitation. Applicants respectfully traverse this rejection.

In the paragraph spanning pages 8 and 9 of Applicants' amendment filed 7/6/06, Applicants clearly indicate that the amendment to claim 32 is supported by the disclosure at page 13. In particular, page 13 indicates that the disclosed adjuvants

"are advantageous in that they induce a cytotoxic T lymphocyte response to the particular antigen. The incorporation of such adjuvants in the subject compositions may further enhance the immunological response related to the target antigen."

Thus, the recitation of "an adjuvant which induces a cytotoxic T lymphocyte response to the selected antigen of (i)" is explicitly supported by the specification as originally filed.

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It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

II. Rejection of Claims Under 35 U.S.C. §103

Claims 32-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Anand et al. (U.S. Patent No. 6,291,208) and Heath (U.S. 2002/0135722) in view of Maraskovsky et al. (U.S. Patent No. 6,497,876) and Smith et al. (U.S. Patent No. 6,509,313) for the reasons of record. Applicants respectfully traverse this rejection.

MPEP §2143 indicates that to establish a *prima facie* case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The cited prior art references fail to meet these three basic criteria.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). MPEP §2143.01. The Examiner has acknowledged in this, and the prior Office Action, that the primary reference does not teach the use of adjuvants. In this regard, while Anand et al. teach antibody conjugates, this reference does not provide adequate direction or advantages to include an adjuvant in the composition disclosed

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therein. Further, as indicated in Applicants' amendment filed 7/6/06, Anand et al. repeatedly opine about the advantages of the disclosed composition in the absence of conventional adjuvants. Thus, there is no substantial evidence of a desirability and therefore motivation to provide an adjuvant with the composition of Anand et al.

Moreover, while the Examiner suggests at page 5 of the Office Action that Anand et al. teach "enhancing immune responses in the absence of conventional adjuvants, this teaching does not preclude the ordinary artisan to apply adjuvants, including combinations of certain types of adjuvants, such as cytokines, in boosting immune responses to antigens of interest," a general incentive does not make obvious a particular result, nor does the existence of isolated techniques by which that particular result can be obtained. See *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995).

Accordingly, the statements made by the Examiner amount to no more than conclusory statements of generalized advantages and convenient assumptions about skilled artisans. However, such statements and assumptions are inadequate to support a finding of motivation, which is a factual question that cannot be resolved on "subjective belief and unknown authority." *Lee*, 277 F.3d at 1344. Therefore, Applicants respectfully submit that the Examiner has not met the first criterion for establishing a *prima facie* case of obvious under 35 U.S.C. 103(a).

Likewise, it is respectfully submitted that the cited prior art references fail to meet the third criterion for establishing a *prima facie* case of obvious, i.e., the prior art reference (or references when combined) must teach or suggest all the claim

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limitations. In this regard, the instant method requires "an adjuvant which induces a cytotoxic T lymphocyte response to the selected antigen of (i)." While the combined teachings of Heath, Maraskovsky et al. and Smith et al. provide the use of cytokines to induce proliferation of B-cells and isotype switching, these references, as well as Anand et al., fail to teach or suggest an adjuvant which induces a cytotoxic T lymphocyte response to a selected antigen.

MPEP §2143.03 states that all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). In this regard, Applicants respectfully submit that the combined teachings of the cited references fail to teach or suggest the all the limitations of the claims and therefore cannot be held to make the present invention obvious.

Because there is no teaching, suggestion or motivation to combine the referenced teachings and the cited references further fail to teach or suggest all claim limitations, a *prima facie* case of obviousness has not been established. It is respectfully requested that this rejection be reconsidered and withdrawn.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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